

Remarks

Claims 16-19, 28, and 32-35 are amended, claim 31 is cancelled, and claims 36-39 are added. Claims 1-30 and 32-39 are pending.

In response to the Restriction Requirement mailed March 22, 2004, Applicant elects, with traverse, the claims in Group II (claims 16-19, 28 and 31-35, and new claims 36-39), directed to a method of identifying a human at risk of, or having, an indication associated with altered innate immunity, and a method to detect a polymorphism in a human TLR4 gene. Reconsideration of the Restriction Requirement in view of the remarks presented below is respectfully requested.

The Restriction Requirement is traversed on the basis that the inventions are so closely related. For instance, claims directed to a method in which the presence of human nucleic acid encoding a variant TLR4 is detected or determined (claims 16-19, 28 and 31-39; Group II) are clearly related to claims directed to an isolated and purified DNA molecule comprising a human genomic DNA encoding TLR4, a biologically active fragment or a variant thereof; an isolated and purified nucleic acid molecule comprising a human nucleic acid segment encoding a variant TLR4, or a biologically active fragment thereof; an expression cassette comprising a promoter operably linked to a human DNA segment encoding a variant TLR4, or a biologically active fragment thereof; a host cell augmented by a nucleic acid molecule of the invention; and methods to prepare a variant TLR4 polypeptide (claims 1-15; Group I); claims directed to an isolated, variant human TLR4 polypeptide or a biologically active fragment thereof (claims 20-22; Group III); and a claim directed to a transgenic mouse encoding human TLR4 which is expressed so as to result in the transgenic mouse having altered innate immunity relative to a corresponding nontransgenic mouse (claims 29-30; Group VII).

The Restriction Requirement is also traversed on the basis that restriction requirements are optional in all cases. M.P.E.P. § 803. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it arguably may include claims to distinct or independent inventions. M.P.E.P. § 803. In light of this, it is submitted that Applicant should not be required to incur the additional costs associated with the filing of divisional applications in order to obtain protection for the claimed subject matter. In particular, evidence that the search and examination of the claims in at least Group II

and Group I can be efficiently and effectively searched is provided in the Restriction Requirement, as the claims in Group II and Group I fall within the same class (class 435) for search purposes. Thus, it is respectfully submitted that the claims of Groups II and I can be efficiently and effectively searched in a single search with no additional burden placed on the Examiner. Accordingly, reconsideration and withdrawal of the Restriction Requirement is respectfully requested.

The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding this Response or if prosecution of this application may be assisted thereby.

Respectfully submitted,

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By their Representatives,

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MAY 5, 2004

By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this

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